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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet 1

1

of 2

2

**Complet if Known**

Application Number	10/828.483
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Filing Date	April 16, 2004
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First Named Inventor	Cavaleri
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Art Unit	1614
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Examiner Name	Not yet assigned
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Attorney Docket Number	892.280-147
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## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

G. Peahr

Date Considered

14/8/04

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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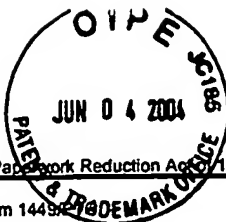
Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
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		Filing Date	April 16, 2004
		First Named Inventor	Cavaleri
		Art Unit	1614
		Examiner Name	Not yet assigned
Sheet 2	of 2	Attorney Docket Number	892,280-147

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CP	C1	A. MALABARBA et al, "Glycopeptide derivatives", Current Medicinal Chemistry, Vol. 8, 2001, pp. 1759-1773	
CP	C2	T. STAROSKE et al, "Synthesis of covalent head-to-tail dimers of vancomycin", Tetrahedron Letters, Vol. 39, 1998, pp. 4917-4920	
CP	C3	G. CANDIANI et al., "In-vitro and in-vivo antibacterial activity of BI 397, a new semi-synthetic glycopeptide antibiotic", Journal of Antimicrobial Chemotherapy, Vol. 44, 1999, pp. 179-192	

Examiner Signature	<i>E. Pearl</i>	Date Considered	12/8/04
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PTO/SB/08B (08-03)

Approved for use through 07/31/2008. OMB 0651-0031

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Sheet 1 of 1

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G	1	Dowell, et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," 2003 ECCMID Meeting.	
G	2	Stogniew et al. (2003). "Pharmacokinetic Attributes of Dalbavancin: Well Distributed and Completely Eliminated With Dual Routes of Elimination," 2003 ECCMID Meeting.	
G	3	White et al. (2000). "V-Glycopeptide: Phase1 Single and Multiple-dose Placebo Controlled Intravenous Safety, Pharmacokinetic, and Pharmacodynamic Study in Healthy Subjects," Abstracts of the 40th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 2000, page 233.	

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G. Puleo

Date  
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12/7/05

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Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket N . 892,280-147

Application No.: Not Yet Assigned

Applicant: CAVALERI et al.

Filing Date: Submitted h rewith

Group Art Unit: Not Yet Assigned

Mailing Date: April 16, 2004

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
GP	1.	03/25/1980	4,195,079	Celmer et al.			
GP	2.	12/16/1980	4,239,751	Coronelli et al.			
GP	3.	09/17/1985	4,542,018	Borghi et al.			
GP	4.	04/28/1987	4,661,470	Malabarba et al.			
GP	5.	11/01/1988	4,782,042	Selva et al.			
GP	6.	09/19/1989	4,868,171	Selva et al.			
GP	7.	11/21/1989	4,882,313	Sitrin			
GP	8.	04/03/1990	4,914,187	Malabarba et al.			
GP	9.	06/19/1990	4,935,238	Selva et al.			
GP	10.	09/04/1990	4,954,483	Malabarba et al.			
GP	11.	07/09/1991	5,030,619	Hector			
GP	12.	11/12/1991	5,064,811	Borghi et al.			
GP	13.	02/25/1997	5,606,036	Hermann et al.			
GP	14.	05/12/1998	5,750,509	Malabarba et al.			
GP	15.	12/01/1998	5,843,679	Selva et al.			
GP	16.	03/16/1999	5,882,900	Rizzo et al.			
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GP	19.	08/10/1999	5,935,238	Talcott et al.			
GP	20.	12/28/1999	6,008,225	Lociuro et al.			
GP	21.	11/07/2000	6,143,739	Lociuro et al.			
GP	22.	04/17/2001	6,218,505	Panzone et al.			
GP	23.	05/07/2002	6,384,013	Burkhardt et al.			

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Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO	
Ly	24.	02/16/1983	EP 0 071 970	Europe				
Ly	25.	11/30/1983	EP 0 095 154	Europe				
Ly	26.	04/16/1986	EP 0 177 882	Europe				
Ly	27.	12/10/1986	EP 0 204 179	Europe				
Ly	28.	07/08/1987	EP 0 228 015	Europe				
Ly	29.	10/14/1987	EP 0 240 609	Europe				
Ly	30.	03/16/1988	EP 0 259 781	Europe				
Ly	31.	02/01/1989	EP 0 301 785	Europe				
Ly	32.	05/24/1989	EP 0 316 712	Europe				
Ly	33.	07/04/1990	EP 0 376 041	Europe				
Ly	34.	02/03/1993	EP 0 525 499	Europe				
Ly	35.	10/15/1997	EP 0 801 075	Europe				
Ly	36.	07/28/1999	EP 0 931 834	Europe				
Ly	37.	12/21/1983	GB 2 121 401	Great Britain				
Ly	38.	02/15/1984	GB 2 142 234	Great Britain				
Ly	39.	02/01/1989	JP 1050900	Japan			Abstract	
Ly	40.	04/21/1988	WO 88/02755	WIPO				
Ly	41.	10/04/1990	WO 90/11300	WIPO				

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(including author, title, Date, Pertinent Pages, Etc.)

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Ly	42.	Abramson, M.A. and Sexton, D.J. (1999). "Nosocomial Methicillin-Resistant and Methicillin-Susceptible <i>Staphylococcus Aureus</i> Primary Bacteremia: At What Costs?" <i>Infect. Control Hosp. Epidemiol.</i> 20(6): 408-411.
Ly	43.	Adamczyk, M. et al. (1999). "Investigations Into Self-Association of Vancomycin Covalent Dimers Using Surface Plasmon Resonance Technology," <i>Bioorganic &amp; Medicinal Chemistry Letters</i> 9:2437-2440.

EXAMINER:

Ly. Peck

DATE CONSIDERED:

2/8/05

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44.	44.	Ahrendt, K.A. et al. (2003). "Identification of Potent and Broad-Spectrum Antibiotics from SAR Studies of a Synthetic Vancomycin Analogue," <i>Bioorganic &amp; Medicinal Chemistry Letters</i> 13:1683-1686.	
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46.	46.	Anderegg, T.R. et al. (2003). "Initial Quality Control Evaluations for Susceptibility Testing of Dalbavancin (BI397), an Investigational Glycopeptide with Potent Gram-Positive Activity," <i>J. Clin. Microbiol.</i> 41(6): 2795-2796.	
47.	47.	Anderegg, T.R. et al. (2003). "Multicenter Quality Control Evaluation Results for Dalbavancin (BI 397), An Investigational Glycopeptide with Potent Gram-Positive Activity," <i>ASM May 2003, Poster No. A-090</i> , one page.	
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56.	56.	Barna, J.C.J. and Williams, D.H. (1984). "The Structure and Mode of Action of Glycopeptide Antibiotics of the Vancomycin Group," <i>Ann. Rev. Microbiol.</i> 38:339-357.	
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58.	58.	Campbell, K.C.M. et al. (2003). "Audiologic Monitoring for Potential Ototoxicity in a Phase I Clinical Trial of a New Glycopeptide Antibiotic," <i>J. Amer. Acad. Audiology.</i> 14(3):157-168.	
59.	59.	Candiani, G. et al. (1999). "In-Vitro and In-Vivo Antibacterial Activity of BI 397, a New Semi-Synthetic Glycopeptide Antibiotic," <i>J. Antimicrob. Chemother.</i> 44:179-192.	
<b>EXAMINER:</b> <i>G. Peck</i>		<b>DATE CONSIDERED:</b> <i>2/18/04</i>	
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60.	Cavaleri, M. et al. (2002). "Protein Binding of Dalbavancin Using Isothermal Titration Microcalorimetry," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1385, pg. 18.
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62.	Chaix, C. et al. (1999). "Control of Endemic Methicillin-Resistant <i>Staphylococcus Aureus</i> ," <i>JAMA</i> 282(18):1745-1751.
63.	Crowe, M. et al. (1998). "Bacteraemia in the Adult Intensive Care Unit of a Teaching Hospital in Nottingham, UK, 1985-1996," <i>Eur. J. Microbiol. Infect. Dis.</i> 17: 377-384.
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65.	Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. Abstract No. 52, pg. 53.
66.	Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. <b>Poster No. 52</b> , one page.
67.	Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , Abstract No. P1224. Vol. 9(Supp. 1), p. 291.
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69.	Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1386, pg. 18.
70.	Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC</i> , San Diego, CA, September 27-30, 2002. <b>Poster No. A-1386</b> , one page.
71.	Dowell, J.A. et al. (2003). "Dalbavancin (DAL) Pharmacokinetics (PK) in Subjects With Mild or Moderate Hepatic Impairment (HI)," <i>43rd. Annual ICAAC</i> , Chicago, IL, September 14-17, 2003. <b>Poster #A-19</b> , one page.
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73.	Fieser, L.F. and Fieser, M. (1967). <i>Reagents for Organic Synthesis</i> John Wiley and Sons, Inc. pp. 128-130.

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S. Peale

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67	74.	Fridkin, S.K. et al. (2003). "Epidemiological and Microbiological Characterization of Infections Caused by Staphylococcus Aureus with Reduced Susceptibility to Vancomycin, United States, 1997-2001," <i>Clinical Infectious Diseases</i> 2003 36: 429-439.
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67	82.	Goldstein, D. et al. (May 22, 2001). "Versicor Begins Phase II Trial of Dalbavancin, Its Noval Glycopeptide Antibiotic." Press Release, three pages.
67	83.	Goldstein, D. et al. (December 17, 2001). "Versicor Announces Positive Phase I Data for Dalbavancin, Demonstrating Feasibility of Once-Weekly Dosing." Press Release, four pages.
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67	85.	Goldstein, D. et al. (September 19, 2002). "Versicor Announces 24 Abstracts to be Presented at Annual ICAAC Meeting Next Week." Press Release, three pages.
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67	88.	Goldstein, E.J.C. and Citron, D.M. (2002). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Fastidious and Anaerobic Gram-Positive Species," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27 - 30, 2002. Abstract No. E-1454, pg. 163.

<b>EXAMINER:</b> <i>E. Peck</i>	<b>DATE CONSIDERED:</b> <i>12/8/04</i>
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G	89.	Goldstein, E.J.C. et al. (2003). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Anaerobic Gram-Positive Species and Corynebacteria," <i>Antimicrob. Agents and Chemother.</i> 47(6): 1968-1971.	
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EXAMINER: <u>G. Pearl</u>	DATE CONSIDERED: <u>12/7/04</u>
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